Paper No. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN B. SULLIVAN, and FINDLAY E. RUSSELL

Appeal No. 2001-1255
Application No. 08/405,454

ON BRIEF

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 40-42 and 45-47, which are all the claims pending in the application.

Claims 40 and 45 are illustrative of the subject matter on appeal and are reproduced below:

40. An antivenom composition comprising Fab fragments which bind specifically to a venom of a snake of the Crotalus genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier.

45. Fab fragments which bind specifically to a venom of a snake of the Crotalus genus, and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using an anti-Fc antibody.

The references relied upon by the examiner are:

Stedman's Medical Dictionary (Stedman's) 94 (23rd ed., Williams and Wilkins Co., 1976)

Smith et al. (Smith), "Immunogenicity and kinetics of distribution and elimination of sheep digoxin-specific IgG and Fab fragments in the rabbit and baboon," Clin. Exp. Immunol., Vol. 36, pp. 384-96 (1979)

Sullivan et al. (Sullivan), "Isolation and Purification of Antibodies to Rattlesnake Venom by Affinity Chromatography," Proc. West. Pharmacol. Soc., Vol. 25, pp. 185-92 (1982)

Coulter et al. (Coulter), "Simplified Preparation of Rabbit Fab Fragments," J. Immunol. Methods, Vol. 59, pp. 199-203 (1983)

GROUNDS OF REJECTION

Claims 40-42 and 45-47 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention.

Claims 40-42 and 45-47 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter, Smith and Stedman's.

Claims 45-47 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter.

We reverse the rejection under 35 U.S.C. § 112, first paragraph. We vacate the rejection of claims 40-42 and 45-47 under 35 U.S.C. § 103 over Sullivan in view of Coulter, Smith and Stedman's. We affirm the rejection of claims 45-47 under 35 U.S.C. § 103 over Sullivan in view of Coulter.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 4), "[t]here is no support in the specification as originally filed for the recitation of 'essentially free from contaminating Fc' in claims 40 and 45." According to the examiner (id.) the original specification and claims "recite that the claimed F(ab) produce an electrophoresis [pattern] wherein no precipitation band against anti-Fc antibodies is seen." While the examiner agrees (Answer, page 9) with appellants (Brief, page 10) that the specification discloses "that digesting an antibody molecule with papain for only four hours results in fragments that produce, 'a slight hint' of a F(c) reaction," the examiner maintains (Answer, page 10) that "[t]he term 'essentially free from contaminating Fc' is not defined in the specification."

While we agree with the examiner (Answer, page 9), that "the term 'consisting essentially of' and 'essentially free' are not," as appellants argue (Brief, page 15) synonymous, we disagree with the examiner's conclusion (Answer, pages 9-10), based on In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), that "there is no disclosure in the specification that the claimed invention would be limited to Fc present in 'unavoidable levels of impurities but not more'."

When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the application when filed as the invention of the appellants.

In re Richard Wright, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1988) (emphasis in original). This is the essence of the description requirement of section 112, first paragraph: whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the "later" claimed invention in the specification as filed. See Texas Instruments Inc. v. U.S. International Trade Commission, 871 F.2d 1054, 1062, 10 USPQ2d 1257, 1262-63 (Fed. Cir. 1989); Wesphal v. Fawzi, 666 F.2d 575, 577, 212 USPQ 321, 323 (C.C.P.A 1981). (Amended claims are reviewed to determine if they are supported in the original disclosure under 35 U.S.C. §112, first paragraph. If the amended claim is not supported in the original specification, the claim will be rejected.).

We recognize the examiner's reliance on Marosi, wherein the examiner extrapolates (Answer, page 10) the holding in Marosi to the facts in this case finding no disclosure that "the claimed invention would be limited to Fc present in 'unavoidable levels of impurities but not more'." In our opinion, Marosi, does not, as the examiner apparently believes (see, pages 9-10), stand for the proposition that the phrase "essentially free of" is defined as unavoidable levels of impurities but not more. Instead, the court in Marosi, held "[c]laims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.'" On this record both the examiner and appellants agree that the specification discloses that "digesting an antibody molecule with papain for only four hours results in fragments that produce 'a slight hint of a F(c) reaction.'" Brief, page 10. It

appears to us that the question is whether a person of ordinary skill in the art would appreciate that the phrase "a slight hint of a F(c) reaction" could also be stated as "essentially free from contaminating Fc." In contrast to the examiner's opinion, we believe that a person of ordinary skill in the art reading appellants' claimed invention in light of the specification would have realized that appellants' disclose both the conditions wherein the Fab preparation is completely free from contaminating Fc (specification, bridging sentence, pages 16-17); and wherein an incomplete (four hour) papain digestion will result in a Fab preparation that has a "slight hint" of contaminating Fc. However, as appellants explain (Brief, page 12):

> Given their goal of reducing serum sickness by removing Fc fragments from the Fab fragments ... [a]ppellants ... recognized that the slight hint of an Fc reaction seen with the four-hour digest was so small as to not be a major concern, so that their preferred digestion period included, as a lower limit, four hours.

See specification, page 17, lines 34-35. As we understand the claimed invention, a four-hour digest with papain will produce a Fab preparation that, while not completely free from contaminating Fc, is essentially free from contaminating Fc. Specification, page 17.

In determining whether a disclosure complies with the written description provision of 35 U.S.C. §112, first paragraph, each case must be decided on its own facts. In re Driscoll, 562 F.2d 1245, 1248-50, 195 USPQ 434, 436-438 (CCPA 1977). On the particular facts of this case, it is our opinion that the specification provides an adequate written description of the claimed invention.

Accordingly, we reverse the rejection of claims 40-42 and 45-47 under 35 U.S.C. § 112, first paragraph.

THE REJECTIONS UNDER 35 U.S.C. § 103:

Sullivan in view of Coulter, Smith and Stedman's:

The examiner finds that (Answer, page 5) Sullivan "teach[es] purified antivenin polyvalent antibodies derived from horse hyperimmune antisera against venom of the Crotalus genus...." The examiner recognizes, however, that Sullivan does not teach F(ab) containing antivenin. Id. To make up for this deficiency the examiner relies on Coulter, Smith and Stedman's.

According to the examiner (id.), Coulter teaches "a method for producing [antivenin[1]] F(ab) fragments that are free of Fc...." The examiner finds (id.), "[t]he F(ab) produced by said method were free of Fc and extraneous protein." Apparently believing that the intended use of the composition, as an antivenom, set forth in the preamble of the claim provides some patentable distinction over the Fab fragments in PBS taught by the combination of Sullivan in view of Coulter, the examiner relies on Smith (Answer, page 6), to teach "the advantages of F(ab) fragments for the neutralization and clearance of toxic substances in therapeutic applications."

[1] The examiner explains (Answer, page 5) that Coulter teach a composition of F(ab) fragments of antibody against textilotoxin (a snake toxin). Since Stedman's defines antivenin as "an antitoxin specific for an animal or insect toxin", the examiner reasons that Coulter teach an antivenin.

In response, appellants argue that the rejection is based upon hindsight reconstruction of the teachings in their specification, and that the rejection lacks a reasonable expectation of success. Brief, page 18. Appellants then spend the next 11 pages of their Brief discussing why a person of ordinary skill in the art would not have relied upon the references cited by the examiner to produce the claimed antivenom.

We remind both the examiner and appellants, that the "mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable." In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Stated differently, "the compositions ... would not undergo a metamorphosis to a new composition by labeling its container to show that it is a composition suitable for treating peanuts to avoid the formation of pops and unsound kernels." In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). In our opinion, both the examiner and appellants place far to great a weight on the term "antivenom" in the preamble of this claimed composition. Accordingly, we vacate the rejection in view of the new ground of rejection set forth infra.

Sullivan in view of Coulter:

According to appellants (Brief, page 8), the claims stand or fall with respect to each separate ground of rejection. Therefore, we limit our discussion to representative independent claim 45. Claims 46 and 47 will stand or fall together with claim 45 with regard to these rejections. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

The examiner finds (Answer, page 7), Sullivan "teach[es] purified antivenin polyvalent antibodies derived from horse hyperimmune antisera against venom of the Crotalus genus...." The examiner recognizes, however, that Sullivan do not teach F(ab) containing antivenin. Id. To make up for this deficiency the examiner relies on Coulter.

According to the examiner (id.), Coulter teaches "a method for producing [antivenin] F(ab) fragments that are free of Fc...." The examiner finds (id.), "[t]he F(ab) produced by said method were free of Fc and extraneous protein." In addition, the examiner finds (Answer, bridging paragraph, pages 7-8), that Coulter teaches "'Fab fragments of IgG have been used in enzyme immunoassay instead of IgG.... EIAs of higher sensitivity have been claimed when Fab ... is used instead of IgG....'" Accordingly, the examiner concludes that a person of ordinary skill in the art would have produced F(ab) fragments against Crotalus venom for use in EIAs to detect said venom since Coulter teaches that F(ab) fragments provide the EIA with a higher degree of sensitivity.

In response, appellants rely on the statements made with regard to the previous rejection, arguing (Brief, page 30), Coulter "used a single venom toxin, not an entire venom, and basic toxicology texts caution against extrapolating from results with single venom toxins (like Coulter et al's) to whole venoms (like the claims recite)." In our opinion, appellants again place too great a weight on one potential use, as an antitoxin, of the claimed "Fab fragments"

Claim 45 is directed to Fab fragments that bind specifically to a venom of a snake of the Crotalus genus, which are essentially free from contaminating Fc

as determined by immunoelectrophoresis using an anti-Fc antibody. There is no requirement in this claim that the Fab fragments exhibit a pharmaceutical activity, therefore, we are not persuaded by appellants' attempt to distinguish their claimed Fab fragments on this basis. Instead, we agree with the examiner's conclusion a person of ordinary skill in the art would have produced F(ab) fragments against Crotalus venom (as taught by Sullivan) for use in EIAs to detect said venom, since Coulter teach that F(ab) fragments provide the EIA with a higher degree of sensitivity. In this regard, we note that Coulter was motivated to prepare Fab fragments due to their "investigation of the binding site(s) of snake neurotoxin at the neuromuscular junction."

Accordingly, we affirm the rejection of claim 45 under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter. As set forth supra, claims 46-47 fall together with claim 45.

New Ground of Rejection

Claims 40-42 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan in view of Coulter. Claim 40 is drawn to an antivenom composition comprising the Fab fragments of appellants' claim 45 and a pharmaceutically acceptable carrier. Claims 41 and 42 further limit the invention to IgG(T) Fab fragments.

As explained above, the mere statement of a new use, in this case "an antivenom" for an otherwise old or obvious composition cannot render a claim to the composition patentable. Zierden, and Pearson. Furthermore, as explained above the combination of Sullivan in view of Coulter teaches the Fab fragments

of claim 45. Therefore, the only remaining element in claim 40 that was not already addressed on this record is the "pharmaceutically acceptable carrier." However, according to Coulter's methodology (page 200) the Fab fragments are recovered in phosphate buffered saline (PBS), a pharmaceutically acceptable carrier. Therefore, for the same reasons set forth by the examiner with regard to claims 45-47[2], we find claims 40-42 prima facie obvious over the combination of Sullivan in view of Coulter.

TIME PERIOD FOR RESPONSE

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision....

[2] We recognize the examiner's statement (Answer, page 7) that the antibodies obtained by Sullivan are "IgG(T), because that is the predominant isotype found in hyperimmune horse antisera." We also recognize that appellants did not dispute this point. Accordingly, we provide no further discussion of claims 41 and 42, which correspond to claims 46 and 47.

37 CFR § 1.196(b) also provides that appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART: 37 CFR § 1.196(b)

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Administrative Patent Judge)
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Donald E. Adams) BOARD OF PATENT
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